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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/882,431	06/25/1997	ROBERT G. ULRICH	003/037/SAP	4135

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/882,431

Applicant(s)

ULRICH ET AL.

Examiner

Marianne P. Allen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-6, 12-14 and 21-23 is/are allowed.
- 6) ☒ Claim(s) 1, 18, 43-44, 53, 62, and 110 is/are rejected.
- 7) ☒ Claim(s) 29-31, 37-39, 47-49, 56-58 and 65-67 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-6,12-14,18,21-23,29-31,37-39,43,44,47-49,53,56-58,62,65-67 and 110.

DETAILED ACTION

Continued Prosecution Application

The request filed on 7/2/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/882,431 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed 7/2/02 has been entered.

Claim Rejections - 35 USC § 112

Claims 1, 18, 43-44, 53, 62, and 110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

This rejection is maintained for reasons of record.

Claim 1 was previously amended to recite that "at least two amino acids" from several ranges of amino acids were altered to result in particular properties. While applicant has explained the basis for the ranges 18-28, 55-65, 86-96, 89-99, and 205-215, applicant has not explained basis for the combinations of altered amino acids embraced by the claims. For example, there does not appear to be support for altering the combination of amino acid 18 and amino acid 28. For example, there does not appear to be support for altering the combination of amino acids 205 and 215. Applicant must point to basis in the specification supporting the breadth of what is now claimed such that a fair reading of the specification would show its contemplation. The combination of the limitations of altering "at least two amino acids" from the named ranges resulting in the recited functional properties is not supported. Disclosed

examples of particular combinations (for example the exemplified vaccines) does not provide support for a generic claim. Note that the disclosure starting on page 20, lines 8-9, is with respect to **additional** mutation and not mutation of these areas alone. The thrust of the invention is to mutate the hydrophobic loop and polar binding pocket as discussed on page 19.

As set forth previously with respect to claim 110, there is no disclosure in the specification of an embodiment having **every** amino acid in the recited ranges altered. While applicant argues that SEQ ID NO: 5 contains the alterations in the recited ranges, the specification disclosure does not appear to describe SEQ ID NO: 5 as having mutations at each of these positions.

Claim 110 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim has been amended to refer to the DNA fragment according to SEQ ID NO: 6. However, this is confusing as SEQ ID NO: 6 is an amino acid sequence and not a DNA fragment. The claim is further confusing in that it is unclear whether applicant is trying to claim the DNA fragment of SEQ ID NO: 5 or something else. While applicant argues that SEQ ID NO: 5 contains the alterations in the recited ranges, the specification disclosure does not appear to describe SEQ ID NO: 5 as having mutations at each of these positions.

Conclusion

Claims 4-6, 12-14, and 21-23 are allowable.

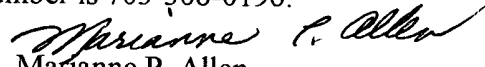
Claims 29-31, 37-39, 47-49, 56-58, and 65-67 are objected to as depending upon rejected claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 9:00 am - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
December 4, 2002